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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/297,899 05/10/99 MARNFELDT

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EXAMINER

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ART UNIT

PAPER NUMBER

3761

DATE MAILED:

06/05/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/297,899

Applicant(s)

Marnfeldt et al.

Examiner

Joseph Weiss

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 10, 1999.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### DETAILED ACTION

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation "the respective at least one switch" in line 14 of the claim.

There is insufficient antecedent basis for this limitation in the claim.

In regards to claims 1-15, the claims are rendered indefinite since in the last line of claim 1 and line 19 of claim 6 applicant sets forth "from one said position to another said position" which is rendered indefinite since the positions set forth previously were a first open position and a second position. Stipulating only said position it is unclear which position applicant is referring to, by saying another position in and of itself is not setting forth that its causing movement from one position to a second DIFFERENT position.

In regards to claim 16, the term vertical is indefinite since it is a relative spacial orientation term, yet no set spacial orientation has been set forth precedent to determine what is vertical and horizontal. Applicant appears to mean longitudinal since the length of the device is greater than its width.

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*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5 & 7-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambrosio et al (5687710).

In regards to claims 1 & 16 Ambrosio discloses an inhaler for delivering medicament (see fig 1-4), with a housing member (120/380/440/320) extending along a vertical (longitudinal?) axis and having an opening (see the opening at the 440 portion which is adapted to engage a user's nares) an inhalation channel (64) that is within the housing member and extending substantially parallel to said vertical axis said inhalation channel member having an inlet portion (vic of elements 90/100 & the metering plate 180), middle portion (portion of 22 between the inlet and outlet portions) and outlet portion (where 22 terminates into the interior of 380), a rotatable dosing unit (22), a dosing element (182) for providing a dose of medicament to the inhalation channel (64), a dose counting unit (580), comprised of a display (330), which is aligned in an opening of the housing which displays usage of the inhaler and which may be outfitted with an electrical circuit (col. 25 lines 23-29) for counting each dose of medicament provided to the inhalation channel and drive the display so as to provide an indication as to the usage of the inhaler, the electrical circuit would include be understood to include a conventional switch arrangement comprised of contact

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elements arranged to have a first open position and a second closed position, when a dose of medicament is provided to the channel, a rotatable member (590) connected to the dosing unit, which is a cam (a rotating or sliding piece in a mechanical linkage) having a camming surface (the surfaces of the various gear teeth 602/604/606), configured to rotate the dosing unit to provide a dose of medicament to the inhalation channel, where the cam will be in physical contact with a contact element and is capable of causing movement of a contact element respective of the at least one switch from an open position to a closed position (see figs 67-82 & 93-104) or where the contact element is locatable within the path of travel of the cam for first and second position displacement, but Ambrosio does not disclose the display being "electronic" and connected to the electric circuit and the electric counting mechanism as set forth by applicant. However, Wolf discloses such electronic display (1035). The references are analogous since they are from the same field of endeavor, the inhaler arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Wolf and used them with the device of Ambrosio when using an electronic switch. The suggestion/motivation for doing so would have been to since Wolf discloses a electronic display for displaying the count of doses counted by an electronic switch on an inhaler, and since Ambrosio discloses the use of an electronic dose counting means with its inhaler (col. 25, lines 23-28). Therefore it would have been obvious to combine the references to obtain the instant application's invention.

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In regards to claim 2, the device suggested by Ambrosio & Wolf discloses the use of two switches (435 & 436 Wolf & Ambrosio notes that plural contact elements can be used).

Furthermore, it is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this duplication of a known part for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 3 & 4, the reference noted above substantially disclose the claimed invention except for the use of a plurality of dosing elements/cams & cam surfaces, i.e. the duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this duplication of a known part for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Also in regards to claims 3 & 4, the reference noted above substantially disclose the claimed invention except for the maintenance of a constant angular spacing.

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It is noted that applicant's specification does not set forth this constant angular spacing, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of a constant angular spacing of the cams/cam surfaces to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claim 5, the device suggested by Ambrosio & Wolf discloses the rotational off setting of switches (see e.g. 435 & 436, figs 4a & 4b).

In regards to claims 7 & 8, the reference noted above substantially disclose the claimed invention except for the use of a resilient biasing arm with a first portion for riding on the cam surface and a second portion for providing a contact means to facilitate lateral movement.

It is noted that applicant's specification does not set forth this arrangement/feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this arrangement/feature to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather

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that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 9, the reference noted above substantially disclose the claimed invention except for the use of a bend in a contact arm.

It is noted that applicant's specification does not set forth this feature, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of a bent contact arm to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 10, Ambrosio substantially discloses the instant application's invention to include the use of a shaft (188) with a surface (190) providing an external/internal spline & another element (218) with surface (222) providing another external/internal spline so that when engaged they facilitate the dosing unit and the rotatable member to be rotated co-commitment, however these elements are not directly part of the dosing unit & rotatable member, as set forth by applicant, i.e. a reversal or rearrangement of known parts for a known purpose.



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It is noted that applicant's specification does not set forth this reversal or rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of this reversal or rearrangement of known parts for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

In regards to claims 11-13, Wolf discloses the display as displaying doses used, doses remaining and is fully capable of being programmed to alternatively display dosage information (col. 13 lines 46-67).

In regards to claim 14, Wolf discloses the display as being an LCD display (1035, col. 13 line 52).

In regards to claim 15, Ambrosio & Wolf discloses a grip so the user may grip the device and rotate it to actuate the dosing mechanism (110 of Wolf & 320 of Ambrosio).

#### ***Response to Arguments***

6. Applicant's arguments filed 12 Mar 01 have been fully considered but they are not persuasive.

In regards to the 35 USC 112 definiteness rejections, applicant's amendment is proper and responsive and resolves the issues, therefore the rejections are withdrawn.

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*Allowable Subject Matter*

7. Claim 6 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action.

*Conclusion*

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

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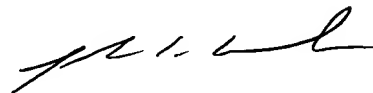
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, John G. Weiss, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



J. Weiss

June 1, 2001



John G. Weiss  
Supervisory Patent Examiner  
Group 3700